

**MONSELS SOLUTION- ferric subsulfate paste**  
**Gynex Corporation**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

**Active Ingredients:**

Ferric Subsulfate...20-22% by weight

Other ingredients include thickeners, preservatives and purified water.

Restricted to use by or on the order of a licensed healthcare professional.

**Single-Use** only. Do not reuse, discard after one use.

Keep cap tightly sealed and away from light.

Store at room temperature (15-30°C).

**PRINCIPAL DISPLAY PANEL**

**Active Ingredients**  
 Ferric Subsulfate... 20 – 22% by weight  
 Other ingredients include thickeners, preservatives, and purified water.  
 Restricted to use by or on the order of a licensed healthcare professional.  
**Single-Use** only. Do not reuse, discard after one use. Keep cap tightly sealed and away from light. Store at room temperature (15 – 30°C). Made in the U.S.A. Distributed by:  
**GYNEX – 1 (888) 486-4644**  
 Redmond, WA 98052

REF 5055      8ml      NDC

**GYNEX®**  
**Monsel's**  
 Ferric Subsulfate Solution

**LOT**

5055 BottleLabel REV C 01.20.10      **CAUTION:** U.S. Federal Law restricts to use by or on the order of a licensed physician.

| <b>MONSELS SOLUTION</b>                                                |                         |                           |                 |
|------------------------------------------------------------------------|-------------------------|---------------------------|-----------------|
| ferric subsulfate paste                                                |                         |                           |                 |
| Product Information                                                    |                         |                           |                 |
| <b>Product Type</b>                                                    | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:48992-001   |
| <b>Route of Administration</b>                                         | TOPICAL                 |                           |                 |
| Active Ingredient/Active Moiety                                        |                         |                           |                 |
| <b>Ingredient Name</b>                                                 |                         | <b>Basis of Strength</b>  | <b>Strength</b> |
| FERRIC SUBSULFATE (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:91O4LML611) |                         | FERRIC CATION             | 210 mg in 1 g   |
| Inactive Ingredients                                                   |                         |                           |                 |
| <b>Ingredient Name</b>                                                 |                         |                           | <b>Strength</b> |

|                                           |  |
|-------------------------------------------|--|
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4) |  |
| <b>FERRIC SULFATE</b> (UNII: 3HWS7HF5XD)  |  |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU) |  |
| <b>WATER</b> (UNII: 059QF0KO0R)           |  |

### Packaging

| # | Item Code        | Package Description                                            | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:48992-001-01 | 14 g in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product | 03/13/2020           |                    |

### Marketing Information

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|------------------------------------------|----------------------|--------------------|
| unapproved drug other |                                          | 03/13/2020           |                    |

**Labeler** - Gynex Corporation (012997685)

### Establishment

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Diversified Chemical Products, Inc. |         | 030317424 | manufacture(48992-001) |

Revised: 3/2020

Gynex Corporation